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Background: The new Inspiron™ (Scitech, Brazil) is a thin-strut (75 μm) cobalt-chromium stent, abluminally coated with a thin (4.4 μg) PLA-PLGA polymeric layer, eluted with low-dose sirolimus. The present study aims to evaluate the safety and efficacy profile of the novel drug-eluting-stent in a very high-risk population treated in a tertiary university hospital.
Methods: Up to May 2014, a total of 276 all-comers, without any specific anatomical or clinical restriction, have been treated with the novel sirolimus-eluing stent implantation and comprise this study population. Patients were maintained in dual antiplatelet therapy for a minimum of 6 months and aspirin was prescribed indefinitely thereafter. Patients have been clinically followed-up at 1, 6 and 12 months post-procedure.
Results: For the entire cohort, a total of 342 lesions were treated with 429 Inspiron™ stents. The included population had a very high risk profile. Overall 53.6% were diabetics, 70.7% had multivessel disease, 39.5% were admitted with acute coronary syndromes, heart failure was present in 16.7%, and 19.2% had previous coronary surgery. Most lesions were type B2/C (79.8%), 31.7% were bifurcations, and 17.6% were restenosis of a previously implanted stent. After a mean follow-up of 136 ± 101 days, the rate of target lesion-related death was 0.5%, myocardial infarction 4.9%, and target lesion revascularization 2.3%. There was only one episode of (probable) stent thrombosis (total any thrombosis rate at 140 days was 0.4%).
Conclusions: The interim results of this real life registry demonstrate promising mid-term safety and efficacy results for the novel Inspiron™ sirolimus-eluing stent in the treatment of highly complex patients.

TCT-609

Comparison of one year outcomes in real world patients treated with a polymer free amphilimus eluting coronary stent versus second generation everolimus eluting stents

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Background: The current study aimed to compare the 1-year clinical outcomes after implantation of the Cre8 (CID/Alvimedica, Saluggia, Italy) amphilimus, polymer-free stent versus new generation everolimus eluting stents (EES) in a real-world patient registry.
Methods: A total of 150 consecutive patients (197 lesions) treated with Cre8 between January 2011 and August 2013 in 4 Italian centers were included. These were propensity matched for baseline characteristics with 150 patients (201 lesions) treated with new generation EES during the same period. Primary outcome was one year major adverse cardiovascular events (MACE), defined as all-cause death, myocardial infarction (MI) and target-vessel revascularization (TVR).
Results: Both groups had similar baseline characteristics including age (67.8±9.8 Cre8 vs. 66.9±9.7 EES years, p=0.393), male gender (84% Cre8 vs. 86.7% EES, p=0.514) diabetes (28% Cre8 vs. 27.3% EES, p=0.972), previous PCI (56% Cre8 vs. 58%EES, p=0.726), previous CABG (22.0% Cre8 vs. 22.7% EES, p=1.000) and previous MI (33.3% Cre8 vs. 31.3% EES, p=0.711). With regards to lesion characteristics there was a higher prevalence of B2/C lesions in the EES group (61.6% vs. 85.4%, P< 0.001) whereas the number of restenotic lesions was similar (13.7% Cre8 vs. 11.0% EES, p=0.413). Total stent length per patient (35.4±25.4mm Cre8 vs. 36.6±26.3mm EES, p=0.667) and SYNTAX score (15.42±9.9 Cre8 vs. 15.28±11.5 EES, p=0.920) were similar in the two cohorts. At one year, MACE rate (7.4% Cre8 vs. 10.2% EES, p=0.261), all-cause mortality (1.3% Cre8 vs. 1.4% EES, p=0.823), TVR (5.2% Cre8, 8.8% EES. P=0.169) and target lesion revascularization-TLR (3% Cre8 vs. 7.4% EES, p=0.108) were not significantly different between the two groups. There was a trend for reduced lesion TLR at one year (3.5% Cre8, vs. 7.3% EES, p=0.055) however this was lost after adjustment for AHA lesion type. In patients with diabetes (Cre8 n=42; EEE n=41) the 1-year TLR was 2.5% in the Cre8 group versus 14.6% in the EES group (p=0.056).
Conclusions: The Cre8 stent is safe and clinically effective, with similar 1-year MACE, TVR and TLR rates as new generation EES in a "real-world" patient registry.

Stents - Drug-eluting: Bioresorbable Scaffolds

Washington Convention Center, Lower Level, Hall A

Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 610-637

TCT-610

Prospective, Multi-Center Evaluation of the DESolve Novolimus-Eluting Bioresorbable Coronary Scaffold: Imaging Outcomes and 2-Year Clinical Results

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Background: The DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) is a drug-eluting bioresorbable scaffold combining a PLLA-based scaffold coated with a biodegradable polylactide-based polymer and Novolimus, a macrocyclic lactone mTOR inhibitor. The DESolve NX study is a prospective, multicenter evaluation of the safety and efficacy of the DESolve NEBCSS in patients with single, de novo, native coronary artery lesions.
Methods: 126 patients receiving the study device were evaluated for multiple clinical endpoints including: major adverse cardiac events-a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization, and stent thrombosis. Endpoints are assessed at 1, 6 and 12 months and annually to 5 years. All patients underwent angiographic assessment at 6 months with a subset of patients having IVUS and OCT at 6 months and MSCT at 12 months.
Results: Mean age at baseline was 62 years, 32% were females, and 21% diabetics. Pre-procedure lesion length was 11.2 mm, RVD was 3.06 mm, and 18.3% of patients had moderate-to-heavy calcification. Six-month QCA imaging demonstrated low mean in-scaffold late lumen loss (0.20 mm), 18.3 %DS and an MLD of 2.45 mm. Serial IVUS imaging (baseline and 6 months) demonstrated a significant increase in mean lumen (Δ 9.0%, p = < 0.001) and scaffold areas (Δ 15.7%, p = < 0.001) and low % volume obstruction (5.05%); and serial OCT imaging demonstrated a significant increase in scaffold area (Δ 16.9 %, p = < 0.001) and 98.78% endothelial coverage of the scaffold at 6 months. Twelve-month MSCT results demonstrated that lumen dimensions (21.8 %DS and 2.3mm MLD) were maintained from 6 to 12 months. Clinical events remained low (MACE = 5.69% at 12 months) with no reports of definite stent thrombosis.
Conclusions: DESolve demonstrated safety and efficacy with low late lumen loss. Serial imaging assessments indicated early vessel restoration at 6 months. At 12 months, the clinical event rate was low, and MSCT demonstrated good luminal patency. Imaging endpoints and 2-year clinical results will be presented.

TCT-611

Multimodality assessment 12 months after implantation of a bioresorbable scaffold for the treatment of culprit lesions in myocardial infarction

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Background: Bioresorbable scaffold (BVS, Absorb, Abbott Vascular) are currently used also for the treatment of acute coronary syndromes, but data on the outcome at the level of the culprit plaque are still missing. Characteristics of a stable plaque include a thick fibrous cap and vasodilation in response to endothelium-dependent vasodilators.
Methods: We describe the 12-months clinical, morphological and functional outcome after BVS implantation for the treatment of culprit lesions in consecutive patients with myocardial infarction. Vasomotion was assessed with infusions of endothelium-dependent acetylcholine and endothelium-independent nitroglycerin.

The morphological assessment was performed with optical coherence tomography (OCT, St Jude).
Results: 71 Patients (77 lesions, 60+/-13 years old, 57 males, 7 diabetics) underwent coronary angiography at 12 months after BVS implantation for acute coronary syndromes (42 NSTEMI, 29 STEMI). OCT was performed in 65 lesions; endothelial function (intracoronary infusions of three different doses of acetylcholine) and endothelium-independent vasodilation (intracoronary nitroglycerin, 200microgr) were tested in 54 patients. Results The culprit lesion was identified in all cases with OCT. The minimum thickness of the fibrous cap covering the lesion was 0 to 550 micrometer (mean 232+/-139microm). Incomplete BVS expansion was evidenced in 20 cases and malapposition in 15. The minimum lumen area was 2 to 11 mm2. There were 3 cases of in-BVS restenosis, maximal neointima thickness was 370+/-220microm), uncovered struts were observed in 12 lesions. Vasodilation beyond the minimum resolution of angiography was observed in 40% of the lesions, and vasoconstriction in 30%.
Conclusions: 12 months after BVS implantation, the presence of a fibrotic cap and of phisiologic vasodilation in response to endothelium-dependent acetylcholine confirm an effective stabilization of the culprit plaque. These data provide a rationale for the use of BVS in the setting of culprit lesions and the basis for a long-term randomized study comparing BVS with traditional metal stents.

TCT-612

Clinical outcomes in patients with calcified lesions, treated with bioresorbable vascular scaffolds

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Background: To date no data exist on clinical outcomes of patients with calcified lesions treated with bioresorbable vascular scaffolds (BVS).
Methods: We analyzed 8-month clinical outcome data of consecutive patients with at least one calcified lesion [defined as calcium arc>60^{o} on IVUS (performed in 78.6% of cases) or in the absence of IVUS at least moderate lesion calcification on angiography] treated with BVS between May 2012 and May 2014. Primary outcome was major adverse cardiovascular event [MACE: defined as all-cause death, myocardial infarction (MI) and target-vessel revascularization (TVR)] rate, at median follow up time.
Results: Out of a total of 163 patients treated with BVS, 62 (38%) had at least one calcified lesion. Mean age of the latter was 63.8±10.5 years and 54 (87.1%) were male. There were 22 (35.5%) patients with diabetes, 3 (4.8%) patients with previous CABG and 31 (50%) with previous PCI. Mean SYNTAX score was 18.89±9.7, whereas left ventricular ejection fraction was 55.5±7.8%. Mean total stent length per patient was 53.3±29.3mm. Of a total of 76 calcified lesions 82.9% were AHA type B2/C, 3.9% were in-stent restenosis, 5.3% were chronic total occlusions and 51.3% were bifurcation lesions. Average calcium arc angle was 189.8±101.2^{o}. Left anterior descending was involved in 67.1% of lesions, circumflex in 19.7%, right coronary artery in 11.8% and left main in 1.3%. Predilatation was performed in all cases with conventional balloons whereas a scoring balloon was used in 26.3% of cases and rotablation in 11.8%. Postdilatation was used in all but one case (98.7%), with an average maximum pressure of 20.7±5.1atm. Minimal luminal area (MLA) increased from 3.18±1.34 pre-procedure to 6.4±1.65 mm^2(minimum stent area) post BVS implantation, p< 0.001. At median follow up of 8.7 (4.9 to 13.4) months 4 (6.5%) MACE occurred. There were no deaths observed, one MI (1.6%), 3 (4.8%) cases of TLR, 4 (6.5%) of TVR and one case (1.6%) of definite late stent thrombosis.
Conclusions: Excellent short term results are observed in patients with calcified lesions treated with BVS. Meticulous lesion preparation is essential.

TCT-613

ABSORB FIRST: An interim report on baseline characteristics and acute performance on the first 1,200 patients from a prospective, multi-center, global registry

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Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb, Abbott Vascular, Santa Clara, CA) has been previously demonstrated with clinical data up to 5 years (Cohort A), 3 years (Cohort B), 2 years (EXTEND). ABSORB FIRST is designed for post-approval surveillance of Absorb BVS used in complex lesions and patients typically treated in real-world settings.
Methods: ABSORB FIRST is a prospective, multi-center, global registry to evaluate the safety and effectiveness of Absorb in the real-world, all-comer population as per Instructions for Use. This study aims to evaluate 1800 patients with de novo lesions at approximately 90 sites in more than 20 countries worldwide. Treatment strategy is determined by physician and limited to lesions in vessels without prior intervention. The key clinical endpoints include scaffold thrombosis, cardiac death, myocardial infarction, revascularization, MACE, TLF, and TVF. All reportable adverse events are 100% monitored and clinical events are independently adjudicated.
Results: This is the largest report of 30-day post-PCI clinical results in Absorb-treated patients from a single trial (ABSORB FIRST, N=1,200). Compared to the Cohort A, B and EXTEND these patients are at greater risks of CAD, higher rates of dyslipidemia (65.8% %), hypertension (64.8%), diabetics (25.1%), family history of premature CAD (37.9%), multi-vessel disease (48.4%), and prior cardiac interventions (24.4%). There is also a high proportion of patients with Class B2/C lesions (48.3 %), moderate/severe calcified lesions (18.6%), bifurcations (12.1%), total occluded lesions (10.4%), ostial lesions (6.2%). The mean lesion length is 18.6 ± 9.2 mm. The device success and procedure success rates were 98.4 % and 97.9 %, respectively. Subgroup analyses by patient and lesion complexities, access site, and physician's treatment techniques and implantation experience with BVS will also be reported. Clinical results up to 30 days will be discussed.
Conclusions: The interim results from this large, global registry demonstrate excellent acute and sub-acute performance of Absorb in complex, real-world patients.

TCT-614

Detailed Morphologic Characterization of the Strut Composition Following Absorb Scaffold Placement in a Porcine Coronary Artery Model Through 48 Months

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Background: The process of bioresorption following Absorb™ bioresorbable vascular scaffold (Absorb, Abbott Vascular) placement has been investigated by optical coherence tomography (OCT) and intravascular ultrasound imaging modalities; however, the details of histomorphological changes within the strut remain poorly characterized. We present detailed histological characterization of the strut composition in porcine coronary arteries from 6 to 48 months (mo).
Methods: A total of 32 Absorb in swine coronary arteries (29 animals) from 8 time points (6, 12, 18, 24, 30, 36, 42, and 48 mo, 4 Absorb from each time point) were evaluated using histologic and immunohistological stains (Figure).
Results: Struts are of stable morphology through 18 mo, being unstained and easily identified under polarized light (Figure). Thereafter, there is rapid decline in birefringence of strut sites and color changes marked by increased proteoglycan staining by Movat and Alcian blue (blue-green, ≥24 mo) and increasing eosinophilia by H&E (≥30 mo). These changes correspond to the absorption and inspissation of proteins (presence of albumin). Strut sites are eventually composed of a provisional matrix that matures from collagen Type III integration (36 mo) to eventual replacement by smooth muscle cells and collagen Type I at 42 to 48 mo, demonstrating an increasing integration of scaffold into the arterial tissue.
Conclusions: Detailed histological characterization of the Absorb struts provides insight into the process of bioresorption and integration that may be correlated to changes observed by in vivo imaging modalities such as OCT.